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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,436	07/16/2001	Hermann Wagner	C1041/7010	1340

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Alan W Steele
Wolf Greenfield & Sacks
Federal Reserve Plaza
600 Atlantic Avenue
Boston, MA 02210-2211

EXAMINER	
WHITEMAN, BRIAN A	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 07/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/786,436	WAGNER ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *104-110,112-113* is/are rejected.

7)☒ Claim(s) *114* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Final Rejection

Claims 104-110 and 112-114 are pending.

Applicant's traversal filed on 4/21/05 is acknowledged and considered by the examiner.

Claim Objections

Claim 114 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 104-110 and 112-113 remain rejected under 35 U.S.C. 103(a) as being unpatentable over McKay et al. (US 5,877,309) taken with Schlom et al. (US 6,045,802).

McKay teaches a method for inhibiting tumors comprising contacting an animal with an oligonucleotide (abstract and columns 3, 4, 17-20, and 33). McKay teaches using an oligonucleotide that is 10-30 nucleotides long comprising the sequence GAGGG, wherein the oligonucleotide sequence does not comprise a CG dinucleotide. See SEQ ID NO: 24 in '309. McKay teaches using oligonucleotide sequences that can be either DNA or RNA (column 6). McKay teaches using oligonucleotides that contain phosphorothioate, methyl phosphonate and peptide bonds and nucleotide derivatives (columns 6-10). McKay teaches using an oligonucleotide having either 13-30 or 17-21 nucleotides (column 6). McKay also teaches that it would be more effective to treat a patient with an oligonucleotide of the invention in conjunction with other traditional therapeutic methods in order to increase the efficacy of a treatment regimen (column 19). However, McKay does not specifically teach using a tumor specific antigen in the method.

However, at the time the invention was made, Schlom teaches that there are several antigens known in the prior art for use in cancer therapy (columns 1-2). Schlom teaches using a tumor specific antigen to expand the number of CTL in vivo, thus improving their effectiveness in eradication of tumors (columns 1, 2 and 11).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of McKay and Schlom to use a tumor-specific antigen in the method taught by McKay. One of ordinary skill in the art would have been motivated to use a tumor specific antigen in the method taught by McKay because a tumor specific antigen would improve the effectiveness of the method taught by McKay for treating a tumor in a subject.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Applicant's arguments filed 4/21/05 have been fully considered but they are not persuasive.

Applicant argues that McKay is directed to inhibiting JNK expression and JNK is often activated as part of mounting an immune response. In many cell types of the immune system, including T cells in particular, upregulation of JNK expression plays a pivotal role in inducing an immune response. In contrast, Schlom teaches expressing an antigen so as to elicit and/or upregulate an immune response in a mammal to T-dependent antigens, i.e., to induce or increase an immune response directed against tumor antigen-expressing tumor. Thus, there is no motivation to combine the teaching of McKay and Schlom as these methods appear to be mutually contradictory.

Applicant's argument is not found persuasive because the method taught by McKay is directed to inhibiting JNK2 expression. Applicant's argue that downregulating JNK would result in a decrease upregulation of T cells. However, there are three types of JNKs and there is no evidence of record that inhibiting JNK2 would downregulate the immune response to an antigen because the skilled artisan understands that JNKs have divergent roles in T cell mediated immunity. Arbour et al. teach that mice lacking JNK2 show expansion of T cells (J. Exp. Med., 195, 801-810, 2002). In addition, Sabapathy et al., J. Exp. Med. 193, 317-328, 2001, teach that JNK1 is necessary for efficient T cell proliferation and IL-2 production. Sabapathy et al. also teach that the absence of JNK2 has no effect on mature T cell proliferation (J. Exp. Med. 193, 317-328, 2001). Thus, in view of the art of record, inhibiting JNK2 would appear not to interfere with the immune system responding to an antigen.

In addition, in view of the properties of nucleotides in vivo, there is no evidence of record that administration of SEQ ID NO: 24 would result in SEQ ID NO: 24 being delivered to a sufficient amount of immune system cells and targeting JNK in a sufficient amount of cells to inhibit the immune system's response to an antigen.

Assuming *arguendo* that applicant's argument is correct and McKay and Schlom are not considered enabled then the claimed method would not be considered enabled for the full scope of the method because the method taught by McKay and Schlom is embraced by the claimed invention and the instant specification does not teach the skilled artisan that using the method taught by McKay and Schlom would be inoperable and the claimed method is unpredictable. While it is acknowledged that the claimed method can embrace inoperable embodiments, it is the

specification that should teach the skilled artisan what embodiments are inoperable/operable for practicing the full breadth of the claimed method. See MPEP 2164.08.

With respect to applicant's argument that there would be no reasonable expectation of success in arriving at the instantly claimed invention, the argument is not found persuasive because other than applicant's assertion, there is no evidence of record to support applicant's assertion. See MPEP 2145.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764.

The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE – Art Unit 1635, can be reached at (571) 272-0811.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman
Patent Examiner, Group 1635

AU1632